The article in the original drum was alleged to be misbranded in that its labeling did not bear adequate directions for use, since there were no directions for use on the drum; and in that it had been fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient. The repackaged product was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious in the treatment of chest colds, head colds, sore throat, croup due to colds, pneumonia, rheumatism, all skin diseases, dry, tickling coughs, sinus trouble, hay fever, flu, and that it would penetrate and relieve congestion, were false and misleading since it would not be efficacious for such purposes.

On August 7, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

613. Misbranding of Comfortt Tablets. U. S. v. 196 Boxes each containing 12 Comfortt Tablets. Default decree of condemnation and destruction. (F. D. C. No. 4895. Sample No. 65614–E.)

These tablets, which contained acetophenetidin, aspirin, and caffeine, originally were shipped in bulk, but subsequently were repackaged by the consignee. After such repackaging, the labeling in addition to failure to bear adequate directions for use and the required warning statements, also failed to declare the aspirin present by its common or usual name.

On June 10, 1941, the United States attorney for the District of Colorado filed a libel against the above-named product, alleging that on or about March 30, 1940, a consignment of a drug product labeled in part "Special Compressed Tablets R/2020 Eng. Comfortt" had been shipped from St. Louis, Mo., to College Laboratories, Inc., Denver, Colo., and that thereafter the latter firm had repackaged said product in boxes labeled in part "Comfortt Tablets"; and charging that as so repackaged it was misbranded as follows:

(1) In that it failed to bear adequate directions for use since those appearing on the box, namely, "Take one tablet and repeat in 30 minutes if needed, then one every 2 hours if needed. See your physician promptly if not relieved," did not limit dosage; (2) in that the labeling did not bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since it failed to warn that frequent or continued use might be dangerous, causing serious blood disturbances, and that not more than the recommended dose should be taken; and (3) in that the label did not bear the common or usual names of the active ingredients, since aspirin had been declared by its chemical name of acetylsalicylic acid and not by its common or usual name.

On August 2, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

614. Misbranding of Dye's Compound Tablets and Dye's Laxative Pellets. U. S. v. 8 Dozen Packages of Dye's Compound Tablets and 2 Dozen Packages of Dye's Laxative Pellets. Default decrees of condemnation and destruction. (F. D. C. Nos. 5083, 5084, 5636. Sample Nos. 7678–E, 7679–E.)

The labeling of the laxative pellets failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users. The labeling of both products bore false and misleading curative and therapeutic claims, and the containers were substantially larger than was necessary.

On July 8 and September 11, 1941, the United States attorney for the Southern District of California filed libels against the above-named drugs at Los Angeles, Calif., alleging that they had been shipped in interstate commerce on or about May 8 and 21 and June 10, 1941 by Dr. J. H. Dye Medical Co. from Buffalo, N. Y.; and charging that they were misbranded.

Analyses of samples showed that the compound tablets consisted of plant extractives, including valeric acid and alkaloid-containing plant drugs; and that the laxative pellets consisted essentially of aloin, podophyllum resin, and hydrastis.

The laxative pellets were alleged to be misbranded (1) in that the labeling did not bear adequate directions for use since the directions called for the administration of a laxative over an indefinite period of time; (2) in that the labeling did not bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe duration of administration in such manner and form as are necessary for the protection of users, since the labeling did not warn that frequent and continued

use might result in dependence upon a laxative and that a laxative should not be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and (3) in that the following statements on the label, "To assist in relieving headaches, coated tongue, bad breath, aggravated pimply skin, lassitude, indigestion and other distressing symptoms due to temporary constipation," and similar statements in Spanish, borne on the label, were false and misleading since the article would not be efficacious for the purposes recommended.

Dye's Compound Tablets were alleged to be misbranded in that statements on the label which represented that it would relieve the distressing symptom of functional dysmenorrhea, painful symptoms of certain female functional irregularities, and symptoms such as headache, nervousness, irritability, headache, backache, nausea, debility, rings under the eyes, melancholia, hysteria, loss of appetite, lack of sleep, and pains in various parts of the body; that it would build up physical resistance, improve digestion and assist one in obtaining more nourishment; that it would promote happy life and would increase vitality and personal magnetism, thus making every attractive woman full of animation; and that it was an appropriate preventive and treatment for amenorrhea, dysmenorrhea, menopause, menorrhagia, metritis, and ovaritis, were false and misleading since it contained no ingredients capable of producing such effects. Both products were alleged to be misbranded further in that the containers were so filled as to be misleading.

On August 14 and October 6, 1941, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

615. Misbranding of Fernol Concentrate. U. S. v. 65 Bottles, 144 Bottles, and 237 Bottles of Fernol Concentrate. Default decrees of condemnation and destruction. (F. D. C. Nos. 4797, 6133, 6274. Sample Nos. 43436–E, 43904–E, 62944–E, 62997–E.)

In addition to failure to bear adequate directions for use and warning statements, the labeling of this product also contained false and misleading claims.

On or about June 2 and November 1 and 22, 1941, the United States attorneys for the District of Kansas and the Eastern District of Michigan filed libels against 65 bottles of Fernol Concentrate at Wichita, Kans., and 381 bottles of Fernol Concentrate at Detroit, Mich., alleging that the article had been shipped within the period from on or about February 21 to on or about November 15, 1941, by the Fernol Co. from Chicago, Ill., and from Kansas City, Mo.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of Epsom salt, extract of cascara sagrada, small proportions of magnesium carbonate, sodium phosphate, salt, iron and ammonium citrate, a sugar, saccharin, alcohol, and water.

The portion of the product located at Detroit was alleged to be misbranded: (1) In that the directions for use appearing on the label, "Average Directions for Taking Adults: Take two tablespoonsful before going to bed and one tablespoonful before or after each meal. As this preparation contains laxative as well as other ingredients, regulate the dose according to action on bowels. You should have two thorough bowel actions a day. Above dose is average, but decrease or increase as agreeable," were not adequate directions for use since the article was essentially a laxative drug and the said directions for use included no limitation on the duration of administration but suggested use for an indefinite period by reason of the following statement appearing in an accompanying leaflet, "Valuble Coupon Read Carefully When you have Three of these coupons, mail to Company as below and we will mail you promptly prepaid one bottle of Fernol Free. Just go to your druggist and buy two more bottles of Fernol and you will then have three coupons." (2) In that the statement appearing in an accompanying leaflet, "Send For 'The Fernol Method' Send penny post card or letter to Fernol Co., 800 N. Clark St., Chicago, Illinois for instructive information on the Fernol Method. It will be mailed you postage paid," referred to two other leaflets entitled "The Fernol Method of Weight Reduction" and "Proof," and by such reference incorporated in the labeling of the article the statement appearing in these two leaflets, and that these statements, which represented that the article was a safe or appropriate means of reducing weight, would improve the whole system, overcome arthritis, enable one to do hard work without feeling worn out, prevent one from becoming tired after working all day, make one feel fine, relieve stuffiness around